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510(K) SUMMARY

NOV 2 6 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **Quanta Computer Inc.**
BG1 Medical Devices Department

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Contact: Jason Hung / Title: Specialist 1

2. Device Name :

Trade Name: **Quanta Blood Pressure Meter** ,
Model no.: **Cardiac Elite 1000 (or QH200)**

Common Name: Non-Invasive Blood Pressure Monitor

Classification name System , Measurement , Blood-Pressure , Non-Invasive

3. DEVICE CLASS The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** has been classified as
Regulatory Class: II
Panel: 74
Product Code: DXN
Regulation Number: 2ICFR 870.1130

4. Predicate Device:

- **OMRON Automatic Blood Pressure Monitor, Model HEM-711AC (K052154)** marketed by **Omron Healthcare, Inc.**.
- **A&D LifeSource Automatic Blood Pressure Monitor , Model#UA-767 (K982481)** marketed by **A & D ENGINEERING, INC.**.

5. Intended Use: The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** is intended to measure the blood pressure (systolic and diastolic) and pulse rate by oscillometric method. The measurements are conducted by using an cuff which is wrapped around the upper arm. The device is designed for adult patient population.

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6. Device Description:

The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** is designed to measure the systolic and diastolic blood pressure, and pulse rate (heart of an individual).

The device uses an inflated cuff which is wrapped around the upper arm. The cuff is inflated by an electrical air pump. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by a preset mechanical valve at a constant rate. At any moment of measurement, the user can deflate the cuff. The measurement results are displayed on the LCD.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included EN-1060-1, EN-1060-3, ANSI/AAMI SP-10, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** has the same intended use and similar technological characteristics as the OMRON Automatic Blood Pressure Monitor, Model HEM-711AC (K052154) marketed by Omron Healthcare, Inc., and A&D LifeSource Automatic Blood Pressure Monitor , Model#UA-767 (K982481) marketed by A & D ENGINEERING, INC.. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2008

Quanta Computer Inc.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
2904 N. Boldt Drive
Flagstaff, AZ 86001

Re: K083078
Trade/Device Name: Quanta Blood Pressure Meter, Cardiac Elite 1000
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 13, 2008
Received: October 16, 2008

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at(240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083078

Device Name: **Quanta Blood Pressure Meter ,**
Model no.: **Cardiac Elite 1000 (or QH200)**
Quanta Computer Inc.
BG1 Medical Devices Department

Indications For Use:

The **Quanta Blood Pressure Meter , Model no.: Cardiac Elite 1000 (or QH200)** is intended to measure the blood pressure (systolic and diastolic) and pulse rate by oscillometric method. The measurements are conducted by using an cuff which is wrapped around the upper arm. The device is designed for adult patient population.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083078